

REMARKS

The remarks below are in response to an Office Action mailed on September 24, 2007. Claims 79-83 and 107-108 have been rejected under obviousness-type double patenting over U.S. Pat. No. 5,910,154. Claims 79-83 and 107-108 were also rejected under 35 U.S.C. 102(b) over U.S. Pat. No. 5,496,277 to Termin et al. ("Termin").

Claims 29-36 and 96-106 and 116-120 have been canceled as they were directed to a method invention subject to the earlier restriction requirement. The remaining claims, except those noted above as being rejected, have been withdrawn.

A terminal disclaimer has been filed herewith disclaiming any term over that of the '154 patent. The rejection under obviousness-type double patent has therefore been overcome.

Termin discloses a radially expandable implantable device, including a tubular fixation element 22 and a catheter 16, as shown in Figures 1 and 2. The catheter 16 has a central lumen open to a distal tip 20 "to permit delivery of a drug, in liquid form, to the catheter distal tip from a supply at the proximal end of the catheter." Col. 4; ll. 44-48 of Termin.

The fixation element 22 surrounds the catheter 16 and is of open weave construction, such as braided multiple strands or filaments of resilient stainless steel. A stainless steel ring 26 is secured to the distal end of the fixation element and secures the fixation element to the catheter 16. The fixation element is self expanding. Figure 4 and col. 5; ll. 1-5. It is held in place for deployment by sheath 32 that runs the length of the catheter 16.

Figures 9 and 10 of Termin show a balloon catheter 80 and a balloon 82 mounted under a fixation element 90 for expanding the fixation element into a tissue wall segment 98.

Notably, the purpose of the fixation element is not to filter fluids, but to fix the catheter to the tissue wall so that fluids can be delivered through the catheter. "[T]he open weave construction promotes fibrotic growth near the filaments and spaces between filaments, a long term process which further improves the mounting of the catheter." Col. 5; ll. 56-59 of Termin.

Claim 79 of the present application has been amended to recite the means for filtering as including an expansion frame for supporting a filter mesh. This is unlike the fixation element of Termin which is a single layer, resilient structure comprising braided multiple strands. It would also not be obvious to add a filter mesh to Termin's fixation element. The fixation element, for

one, is not intended for use as a filter. Also, use of the filter mesh with Termin's fixation element would interfere with its fixation function as it would impede the fibrotic growth for mounting of the catheter. The rejection of Claim 79 under 35 U.S.C. 102 has therefore been overcome.

Claim 107 of the present application has been amended to recite the sleeve as supporting a balloon on an outside surface and defining a balloon inflation lumen connected in communication with the balloon. Thus, the restraining mechanism of Claim 107 serves a dual function of applying a restraining force to the plurality of struts of the filter device and supporting an inflation balloon on its outer surface. This dual function avoids the need for an additional invasive opening in the patient for a balloon catheter.

Termin's catheter 16 for supporting the self-expanding fixation element 22 has no balloon. One is not needed in this embodiment, since the fixation element 22 is self-expanding. Alternatively, Termin discloses a balloon catheter 80 for supporting a balloon 82. But, the balloon 82 is for expanding a different type of fixation element 90 which is not self-expanding. In this latter embodiment of Termin, there is no sheath 32, and one is not needed since the fixation element 90 is not self-expanding. Addition of a balloon to an outside surface of the sheath 32 the first embodiment (with the self expanding fixation element 22) of Termin would not be obvious because the fixation element 22 is self-expanding and must be retained within the sheath 32. The rejection of Claim 107 under 35 U.S.C. 102 has therefore been overcome.

Claims 80-83 and 108 depend from, and further patentably distinguish, Claims 79 and 107. The rejection of Claims 80-83 and 108 under 35 U.S.C. 102 has therefore also been overcome.

New Claims 121-145 have been added that depend from Claims 79 and 107, or define over the cited art, and should therefore also be allowable.


### CONCLUSION

In view of the remarks and amendments presented above, it is respectfully submitted that the pending claims of the present invention are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225 (RMI-5730CON6).

Respectfully submitted,

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